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Regulatory Proposal PRO2016-01

Revised Environmental Data Requirements

(publié aussi en français)

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1.0 Introduction

Environmental data submitted to the Health Canada Pest Management Regulatory Agency (PMRA) provides essential insight into the potential impact of a pesticide on the environment and are the foundation of the environmental risk assessment. Environmental data requirements were first developed more than 15 years ago and were recently updated to incorporate scientific advancements and address an overall need for clarity.

The purpose of this proposal is to communicate the revised environmental data requirements to industry and other interested parties. This proposal also presents guidance to assist applicants when preparing the environmental portion of the data package. Revisions presented in the current document would supersede environmental data requirements outlined in Regulatory Directive DIR2003-01, *Organizing and Formatting a Complete Submission for Pest Control Products*.

This proposal applies to conventional pesticides only. Data requirements for the registration of antimicrobial products will be examined at a later time. The registration of non-conventional products is discussed in Regulatory Directive DIR2012-01, *Guidelines for the Registration of Non-Conventional Pest Control Products*.

2.0 Revised Data Requirements

Revised environmental data requirements are presented in Appendix I.

Two aspects were considered when revising the environmental data requirements. First, the relevance and adequacy of each data requirement was examined in light of current science. Also, their classification (required/conditionally required/not required) was updated within the different use-site categories. Main highlights include:

- New data requirements were created to reflect recent updates to the pollinator risk assessment framework.
- Requirements that no longer reflect current risk assessment approaches were eliminated.
- Many data currently classified as CR (conditionally required) were converted to NR (not required) or R (required) to improve the predictability of the data requirements.
- No environmental data are required for some uses.

Overall, the revisions better relate data requirements to the potential for environmental exposure, thereby improving predictability and transparency. Changes should help applicants understand the logic behind data requirements and allow the public to be better informed of the considerations taken during an environmental risk assessment.

The new approach does not lessen our level of scrutiny when evaluating environmental risk but rather streamlines the approach by eliminating studies that are rarely used while clearly identifying studies that are required.

Revisions should not impact our ability to carry out joint reviews and collaborate with other governments. In particular, care was taken in aligning the data requirements as much as possible with those from the United States Environmental Protection Agency.

3.0 Guidance for Applicants

Appendix II, III and IV provide information on when and why certain environmental data are to be included in a data package.

Data requirements are not intended to constitute a rigid list of data to be submitted in all cases, but rather serve as a guide. Some of the required data may not be relevant in certain situations or may not be applicable to all uses within a given use-site category. Conversely, it may be appropriate to supplement the data package with data other than those required in the tables to address issues specific to the pesticide itself or to its use pattern.

4.0 Next Steps

PMRA invites the public to submit written comments on the proposed revisions up to 45 days from the publication of this document. Please forward all comments to PMRA Publications. PMRA will consider all comments received before making a final decision on the revised environmental data requirements.

Appendix I Revised Environmental Data Requirements for All Use-Site Categories

R = Required; CR = Conditionally Required; NR = Not Required. As some use-site categories include uses with varying levels of environmental exposure, the use of the letter R may not necessarily indicate that a study is always required, but that it is quite likely to be required; see guidance for more information. Cells with dashes indicate DACOs (data codes) that serve as placeholders for information to be submitted if available. Rows of cells with no dashes indicate titles (for example, the row for 8.2 Laboratory Studies).

Data Code and Study Title	USC 1	USC 2	USC 3[1]	USC 4	USC 5	USC 6	USC 7	USC 8	USC 9	USC 10	USC 11	USC 12[1]	USC 13	USC 14	USC 15[1]	USC 16	USC 17[2]	USC 18[2]	USC 19[1]	USC 20	USC 21	USC 22	USC 23[2]	USC 24[1]	USC 25	USC 26[1]	USC 27	USC 28[1]	USC 29[1]	USC 30	USC 31	USC 32	USC 33
8 Environmental Chemistry and Fate																																	
8.1 Summaries	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
8.2 Laboratory Studies																																	
8.2.1 Summary of Physicochemical Properties	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
8.2.2 Analytical Methodology																																	
8.2.2.1 Soil	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
8.2.2.2 Sediment	CR	CR	NR	CR	CR	CR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
8.2.2.3 Water	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
8.2.2.4 Biota	CR	CR	NR	CR	CR	CR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	CR	NR
8.2.3 Laboratory Studies of Transformation																																	
8.2.3.1 Summary	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
8.2.3.2 Hydrolysis	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
8.2.3.3 Phototransformation																																	
8.2.3.3.1 Soil	NR	NR	NR	R	NR	NR	R	NR	NR	NR	NR	NR	R	R	NR	R	NR	NR	NR	NR	NR	NR	R	NR	R	NR	R	NR	NR	R	NR	NR	NR
8.2.3.3.2 Water	R	R	NR	R	CR	CR	R	NR	NR	CR	CR	NR	R	R	NR	R	R	CR	NR	NR	NR	R	R	NR	R	NR	R	NR	NR	R	NR	NR	NR
8.2.3.3.3 Air	CR	CR	NR	CR	CR	CR	CR	CR	CR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	CR	CR	CR	CR	NR	CR	NR	CR	NR	NR	CR	CR	CR	CR
8.2.3.4 Biotransformation in Soil																																	
8.2.3.4.2 Aerobic Soil: 20°-30°C	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	CR	CR	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
8.2.3.4.4 Anaerobic Soil: 20°-30°C	NR	NR	NR	R	NR	NR	R	NR	NR	R	R	NR	R	R	NR	R	NR	NR	NR	NR	NR	NR	R	NR	R	NR	R	NR	NR	R	NR	NR	NR
8.2.3.5 Biotransformation in Aquatic Systems																																	
8.2.3.5.4 Aerobic Water/Sediment 20°-30°C	R	R	NR	R	R	R	R	NR	NR	R	R	NR	R	R	NR	R	R	CR	NR	NR	NR	R	R	NR	R	NR	R	NR	NR	R	NR	NR	NR
8.2.3.5.6 Anaerobic Aquatic Sediment 20°-30°	R	R	NR	R	R	R	R	NR	NR	R	R	NR	R	R	NR	R	R	CR	NR	NR	NR	R	R	NR	R	NR	R	NR	NR	R	NR	NR	NR
8.2.3.6 Special Studies Related to Use-Pattern or Formulation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	R	—	—	—	—	—	—	—	—	—	—

Data Code and Study Title	USC 1	USC 2	USC 3[1]	USC 4	USC 5	USC 6	USC 7	USC 8	USC 9	USC 10	USC 11	USC 12[1]	USC 13	USC 14	USC 15[1]	USC 16	USC 17[2]	USC 18[2]	USC 19[1]	USC 20	USC 21	USC 22	USC 23[2]	USC 24[1]	USC 25	USC 26[1]	USC 27	USC 28[1]	USC 29[1]	USC 30	USC 31	USC 32	USC 33
8.2.4 Laboratory Studies of Mobility																																	
8.2.4.1 Summary	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	CR	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
8.2.4.2 Adsorption/Desorption	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	CR	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
8.2.4.3 Soil Column Leaching																																	
8.2.4.5 Volatilization	CR	CR	NR	CR	CR	CR	CR	CR	CR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	CR	CR	CR	CR	NR	CR	NR	CR	NR	NR	CR	CR	CR	CR
8.2.4.6 Special Studies Related to Use-Pattern or Formulation	CR	CR	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	CR	CR	—	—	—	—	—	—	—	—	—	—
8.3 Field Studies of Dissipation/Accumulation																																	
8.3.1 Summary	CR	CR	NR	R	NR	NR	R	NR	NR	R	R	NR	R	R	NR	R	CR	CR	NR	NR	NR	CR	R	NR	R	NR	R	NR	NR	R	NR	NR	NR
8.3.2 Terrestrial	NR	NR	NR	R	NR	NR	R	NR	NR	R	R	NR	R	R	NR	R	NR	CR	NR	NR	NR	NR	R	NR	R	NR	R	NR	NR	R	NR	NR	NR
8.3.3 Aquatic	CR	CR	NR	CR	NR	NR	CR	NR	NR	NR	NR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
8.3.4 Special Studies Related to Intended Use Pattern	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	R	—	—	—	—	—	—	—	—	—	—
8.4 Storage, Disposal and Decontamination																																	
8.4.1 Summary	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
8.5 Other Environmental Fate Studies	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
8.6 Other Studies/Data/Reports																																	
8.6.1 Monitoring	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
8.6.2 Other	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
9 Environmental Toxicology																																	
9.1 Summaries	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	CR	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
9.2 Non-Target Terrestrial Invertebrates																																	
9.2.1 Summaries	NR	NR	NR	R	R	R	R	NR	NR	R	R	NR	R	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	R	NR	NR	R	NR	NR	NR
9.2.3 Earthworms																																	
9.2.3.2 Chronic Toxicity	NR	NR	NR	NR	NR	NR	R	NR	NR	R	R	NR	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	R	NR	NR	NR
9.2.4 Bees/Insect Pollinators																																	
9.2.4.1 Bee Adult Acute Contact Toxicity	NR	NR	NR	R	R	R	R	NR	NR	R	R	NR	R	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	R	NR	NR	R	NR	NR	NR
9.2.4.2 Bee Adult Acute Oral Toxicity	NR	NR	NR	R	R	R	R	NR	NR	R	R	NR	R	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	R	NR	NR	R	NR	NR	NR
9.2.4.3 Bee Larvae Toxicity	NR	NR	NR	R	R	R	R	NR	NR	R	R	NR	R	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	R	NR	NR	R	NR	NR	NR
9.2.4.4 Bee Adult Chronic Toxicity	NR	NR	NR	R	R	R	R	NR	NR	R	R	NR	R	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	R	NR	NR	R	NR	NR	NR
9.2.4.5 Bee Toxicity of Residues on Foliage	NR	NR	NR	CR	CR	CR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.2.4.6 Semi-Field Studies for Pollinators	NR	NR	NR	CR	CR	CR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.2.4.7 Field Studies for Pollinators	NR	NR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.2.4.8 Residue Studies for Pollinators	NR	NR	NR	CR	CR	CR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.2.4.9 Other Pollinator Studies	NR	NR	NR	CR	CR	CR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR

Data Code and Study Title	USC 1	USC 2	USC 3[1]	USC 4	USC 5	USC 6	USC 7	USC 8	USC 9	USC 10	USC 11	USC 12[1]	USC 13	USC 14	USC 15[1]	USC 16	USC 17[2]	USC 18[2]	USC 19[1]	USC 20	USC 21	USC 22	USC 23[2]	USC 24[1]	USC 25	USC 26[1]	USC 27	USC 28[1]	USC 29[1]	USC 30	USC 31	USC 32	USC 33
9.2.5 Predators	NR	NR	NR	R	R	R	R	NR	NR	CR	CR	NR	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR
9.2.6 Parasitoids	NR	NR	NR	R	R	R	R	NR	NR	CR	CR	NR	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR
9.2.7 Other Terrestrial Invertebrates	NR	NR	NR	CR	NR	NR	CR	NR	NR	NR	NR	NR	CR	CR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	NR	NR	NR	NR	NR
9.2.8 Laboratory Studies with an End-Use Product	NR	NR	NR	CR	NR	NR	CR	NR	NR	NR	NR	NR	CR	CR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	NR	NR	NR	NR	NR
9.2.9 Field Studies with an End-Use Product (Other than Pollinators)	NR	NR	NR	CR	NR	NR	CR	NR	NR	NR	NR	NR	CR	CR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	NR	NR	NR	NR	NR
9.3 Non-Target Freshwater Invertebrates																																	
9.3.1 Summary	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	CR	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
9.3.2 *Daphnia* sp. Acute	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	CR	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
9.3.3 *Daphnia* sp. Chronic (Life-Cycle)	R	R	NR	R	NR	NR	R	NR	NR	R	R	NR	R	R	NR	R	CR	CR	NR	NR	NR	R	R	NR	R	NR	R	NR	NR	R	NR	NR	NR
9.3.4 Laboratory Studies with other Species	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.3.5 Laboratory Studies with an End-Use Product	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.3.6 Field Studies with an End-Use Product	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.4 Non-Target Marine Invertebrates																																	
9.4.1 Summary	R	R	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	R	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.4.2 Acute (Crustacean)	R	R	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	R	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.4.3 Mollusk Embryo Larvae	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.4.4 Mollusk Shell Deposition	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.4.5 Chronic (Mollusk or Crustacean)	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.4.6 Laboratory Studies with an End-Use Product	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.4.7 Field Studies with an End-Use Product	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.4.8 Bioconcentration/Depuration (Bivalve or Crustacean)	CR	CR	NR	CR	CR	CR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.5 Fish																																	
9.5.1 Summaries	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	CR	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
9.5.2 Acute Studies																																	
9.5.2.1 Cold Water Fish (Rainbow Trout)	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	CR	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
9.5.2.2 Warm Water Fish (Bluegill Sunfish)	R	R	NR	R	R	R	R			R	R	NR	R	R	NR	R	R	CR	NR			R	R	NR	R	NR	R	NR	NR	R			
9.5.2.3 Other Freshwater Fish Species	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.5.2.4 Marine/Estuarine Fish	R	R	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	R	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.5.2.4.1 Salinity Challenge	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.5.3 Sublethal and Chronic Studies																																	
9.5.3.1 Fish, Early Life Cycle Toxicity Test	R	R	NR	R	NR	NR	R	NR	NR	R	R	NR	R	R	NR	R	CR	CR	NR	NR	NR	R	R	NR	R	NR	R	NR	NR	R	NR	NR	NR
9.5.3.2 Fish, Life Cycle Toxicity Test	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR

Data Code and Study Title	USC 1	USC 2	USC 3[1]	USC 4	USC 5	USC 6	USC 7	USC 8	USC 9	USC 10	USC 11	USC 12[1]	USC 13	USC 14	USC 15[1]	USC 16	USC 17[2]	USC 18[2]	USC 19[1]	USC 20	USC 21	USC 22	USC 23[2]	USC 24[1]	USC 25	USC 26[1]	USC 27	USC 28[1]	USC 29[1]	USC 30	USC 31	USC 32	USC 33
9.5.4 Laboratory Studies with an End-Use Product	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.5.5 Field Studies with an End-Use Product	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.5.6 Bioaccumulation	CR	CR	NR	CR	CR	CR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.6 Wild Birds																																	
9.6.1 Summary	CR	CR	NR	**R**	NR	NR	**R**	NR	NR	**R**	**R**	NR	**R**	**R**	NR	**R**	**R**	NR	NR	NR	NR	CR	**R**	NR	**R**	NR	**R**	NR	NR	**R**	NR	CR	NR
9.6.2 Acute Studies																																	
9.6.2.1 Oral (LD_{50}) Bobwhite Quail	CR	CR	NR	**R**	NR	NR	**R**	NR	NR	**R**	**R**	NR	**R**	**R**	NR	**R**	**R**	NR	NR	NR	NR	CR	**R**	NR	**R**	NR	**R**	NR	NR	**R**	NR	CR	NR
9.6.2.2 Oral (LD_{50}) Mallard Duck	CR	CR	NR	**R**	NR	NR	**R**	NR	NR	**R**	**R**	NR	**R**	**R**	NR	**R**	**R**	NR	NR	NR	NR	CR	**R**	NR	**R**	NR	**R**	NR	NR	**R**	NR	CR	NR
9.6.2.3 Oral (LD_{50}) Other Species	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	NR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	CR	NR
9.6.2.4 Dietary (LC_{50}) Bobwhite Quail	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	NR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	CR	NR
9.6.2.5 Dietary (LC_{50}) Mallard Duck	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	NR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	CR	NR
9.6.2.6 Dietary (LC_{50}) Other Species	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	NR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	CR	NR
9.6.3 Chronic Studies																																	
9.6.3.1 Avian Reproduction, Bobwhite Quail	CR	CR	NR	**R**	NR	NR	**R**	NR	NR	**R**	**R**	NR	**R**	**R**	NR	**R**	CR	NR	NR	NR	NR	CR	CR	NR	**R**	NR	**R**	NR	NR	**R**	NR	CR	NR
9.6.3.2 Avian Reproduction, Mallard Duck	CR	CR	NR	**R**	NR	NR	**R**	NR	NR	**R**	**R**	NR	**R**	**R**	NR	**R**	CR	NR	NR	NR	NR	CR	CR	NR	**R**	NR	**R**	NR	NR	**R**	NR	CR	NR
9.6.3.3 Avian Reproduction, Other Species	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	NR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	CR	NR
9.6.4 Laboratory Studies with an End-Use Product	NR	NR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	NR	NR	NR	NR	NR	CR	NR	CR	NR	CR	NR	NR	CR	NR	CR	NR
9.6.5 Field Studies with an End-Use Product	NR	NR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	NR	NR	NR	NR	NR	CR	NR	CR	NR	CR	NR	NR	CR	NR	CR	NR
9.6.6 Special Studies Related to the Intended Use-Pattern	NR	NR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	NR	NR	NR	NR	NR	CR	NR	CR	NR	CR	NR	NR	CR	NR	CR	NR
9.7 Wild Mammals																																	
9.7.1 Summary	CR	CR	NR	**R**	NR	NR	**R**	NR	NR	**R**	**R**	NR	**R**	**R**	NR	**R**	CR	CR	NR	NR	NR	CR	CR	NR	**R**	NR	**R**	NR	NR	**R**	NR	CR	NR
9.7.2 Field Studies with an End-Use Product	NR	NR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.7.3 Other Studies	NR	NR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.8 Non-Target Plants																																	
9.8.1 Summary	**R**	**R**	NR	**R**	NR	NR	**R**	NR	NR	**R**	**R**	NR	**R**	**R**	NR	**R**	**R**	CR	NR	NR	NR	**R**	**R**	NR	**R**	NR	**R**	NR	NR	**R**	NR	NR	NR
9.8.2 Fresh Water Algae	**R**	**R**	NR	**R**	NR	NR	**R**	NR	NR	**R**	**R**	NR	**R**	**R**	NR	**R**	**R**	CR	NR	NR	NR	**R**	**R**	NR	**R**	NR	**R**	NR	NR	**R**	NR	NR	NR
9.8.3 Marine Algae	**R**	**R**	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	**R**	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.8.4 Terrestrial Vascular Plants	NR	NR	NR	**R**	NR	NR	**R**	NR	NR	NR	NR	NR	**R**	**R**	NR	**R**	CR	CR	NR	NR	NR	NR	CR	NR	**R**	NR	**R**	NR	NR	**R**	NR	NR	NR
9.8.5 Aquatic Vascular Plants	**R**	**R**	NR	**R**	NR	NR	**R**	NR	NR	**R**	**R**	NR	**R**	**R**	NR	**R**	**R**	CR	NR	NR	NR	**R**	**R**	NR	**R**	NR	**R**	NR	NR	**R**	NR	NR	NR
9.8.6 Laboratory Studies with an End-Use Product	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.8.7 Field Studies with an End-Use Product	CR	CR	NR	CR	NR	NR	CR	NR	NR	CR	CR	NR	CR	CR	NR	CR	CR	CR	NR	NR	NR	CR	CR	NR	CR	NR	CR	NR	NR	CR	NR	NR	NR
9.9 Other Studies/Data/Reports	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—

Data Code and Study Title	USC 1	USC 2	USC 3[1]	USC 4	USC 5	USC 6	USC 7	USC 8	USC 9	USC 10	USC 11	USC 12[1]	USC 13	USC 14	USC 15[1]	USC 16	USC 17[2]	USC 18[2]	USC 19[1]	USC 20	USC 21	USC 22	USC 23[2]	USC 24[1]	USC 25	USC 26[1]	USC 27	USC 28[1]	USC 29[1]	USC 30	USC 31	USC 32	USC 33
12.5 Foreign Reviews																																	
12.5.8 Environmental Chemistry and Fate	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
12.5.9 Environmental Toxicology	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
12.7 Applicant Generated Study Reviews																																	
12.7.8 Environmental Chemistry and Fate	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R
12.7.9 Environmental Toxicology	R	R	NR	R	R	R	R	R	R	R	R	NR	R	R	NR	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	NR	R	R	R	R

[1] All uses within these use-site categories are expected to result in minimal environmental exposure. For details, please refer to Appendix II.
[2] Not fully reviewed. Data requirements for the registration of antimicrobial products, such as those found under these use-site categories, will be further reviewed at a later time.

Appendix II Guidance for Applicants: Understanding the Potential for Environmental Exposure

The potential for environmental exposure is the main factor used in determining whether certain data are required to support a pesticide registration and is a key concept to consider when preparing a data package.

Environmental exposure depends on several parameters such as the site of application, the application method and the properties of the pesticide itself. In simple terms, environmental exposure can occur when a pesticide enters the environment.

- *The terrestrial environment*: A pesticide can enter the terrestrial environment through direct application to soil or foliage, deposition of spray drift on terrestrial habitats adjacent to the treatment area, or through leaching from treated material (such as treated seeds or treated wood) into the surrounding soil. When exploring the potential for exposure to the terrestrial environment, consideration should be taken as to whether it is possible for non-target terrestrial organisms to be exposed to the pesticide. Examples of relevant exposure routes for terrestrial non-target organisms may include consumption by birds and mammals of insect and plant material containing the pesticide, contact of earthworms with the pesticide in soil, and contact of beneficial arthropods and pollinators with treated foliage. Other examples include direct spray on pollinators present in the field at the time of application, consumption by pollinators of pollen and nectar containing the pesticide, and spray drift deposited on non-target plants adjacent to the treatment area.
- *The aquatic environment*: A pesticide can enter the aquatic environment through direct application to a water body, deposition of spray drift in aquatic systems, runoff (either dissolved in the runoff water or sorbed to soil particles), discharge of effluent, leaching from the treated material into the surrounding water, etc. Examples of relevant exposure routes for aquatic organisms include the contact of non-target fish, aquatic invertebrates, and algae and vascular aquatic plants with the pesticide in the water column and/or sediment.
- *The atmospheric environment*: The atmospheric environment includes air in the vicinity of the site of application but also pertains to the potential for long-range atmospheric transport and subsequent deposition to areas away from the application site. The potential for pesticide exposure in air is primarily based on the inherent physical and chemical properties of the pesticide.

The amount and type of data required to support the registration of a pesticide will vary. For outdoor and greenhouse uses, environmental data are always required, with more data requirements being triggered as the potential for environmental exposure increases. For uses where minimal environmental exposure is expected, such as for indoor uses, there are no specific environmental data requirements. As with any pesticide, however, PMRA may request data to address an identified concern if an area of concern is identified.

Appendix III Guidance for Applicants: Fate and Behaviour in the Environment

Does not apply to USC 3, 12, 15, 19, 24, 26, 28 and 29, for which no environmental data are required.

DACO = Data Code; TGAI = Technical Grade Active Ingredient; EP = End-Use Product; TP = Transformation Product.

DACO	Guidance
8.1 Summaries	Summaries submitted under this DACO are intended to highlight issues of interest related to the fate of the pesticide in the environment. Information included here should provide context and discussion to assist in the evaluation of the submitted data, and therefore, should not be limited to executive summaries copied from the supporting studies. Information may not be required under this DACO if Tier II and Tier III summaries are submitted under DACO 12.7.
8.2 Laboratory Studies	
8.2.1 Summary of Physicochemical Properties	Required for all outdoor and greenhouse uses. The physicochemical properties of a pesticide can be indicative of certain aspects of its fate and behaviour in the environment and may be used to trigger the requirement of additional data. Predictions based on physical and chemical properties are substantiated, as appropriate, with further information on the fate of the pesticide provided in the data package. Studies related to the physicochemical properties of the pesticide are submitted under Part 2 of the data package for the TGAI. The summary provided here should include such information as: water solubility, vapour pressure, dissociation constant, octanol/water partition coefficient, and UV/visible absorption. *Test substance*: TGAI and major TPs
8.2.2 Analytical Methodology	Analytical methodology provided under this DACO is intended to support post-registration monitoring in environmental media. *Test substance*: TGAI and major TPs as appropriate
8.2.2.1 Soil	Required for all outdoor and greenhouse uses.
8.2.2.2 Sediment	Required when a method in soil is not available and the pesticide is expected to enter surface water.
8.2.2.3 Water	Required for all outdoor and greenhouse uses.
8.2.2.4 Biota	Required when methods in plants and livestock are not submitted under DACO 7.2.1/7.2.2 and there are concerns related to the toxicity of the pesticide or its use pattern. For example, methods in biota may be required when a pesticide is highly toxic to fish, when there are potential concerns related to secondary poisoning of birds, and potential concerns for bioaccumulation.
8.2.3 Laboratory Studies of Transformation	These studies individually examine the different routes of transformation that could affect the fate of the pesticide in the environment and are carried out under controlled laboratory conditions. For each route of transformation, studies provide information such as the rate of transformation of the test substance; the identity, formation and decline of transformation products; and transformation pathways.
8.2.3.1 Summary	No information is required under this DACO if Tier II and Tier III summaries are submitted under DACO 12.7.

DACO		Guidance
8.2.3.2	Hydrolysis	Required for all outdoor and greenhouse uses. Hydrolysis is a basic abiotic process that could potentially affect any pesticide. *Test substance*: TGAI, major TPs as appropriate
8.2.3.3	Phototransformation	Phototransformation studies determine to what extent the pesticide is susceptible to transformation when exposed to sunlight, and identify the resulting transformation products.
	8.2.3.3.1 Soil	Required for some outdoor uses, when the pesticide application will result in deposition at the soil surface. For example, this study would be required for pesticides that are sprayed outdoors on soil or on foliage. Data is not required for indoor uses, greenhouse uses, aquatic uses, soil-incorporated compounds, seed treatments, tree injections or other uses where the pesticide would not be found on the soil surface or for which minimal exposure to light is expected. *Test substance*: TGAI, major TPs as appropriate
	8.2.3.3.2 Water	Required when the pesticide application will result in the pesticide entering surface water. For example, this study would be required for any outdoor aquatic use and for any outdoor terrestrial use where spray drift or runoff would be expected. This study may also be required for greenhouse uses if the pesticide is hydrolytically stable or is not rapidly biotransformed, since greenhouse effluent may be discharged into surface water. Not required for indoor uses and for outdoor uses that are not expected to lead to important residues in surface water such as uses limited to a small area on the outside perimeter of buildings, and most spot treatments. *Test substance*: TGAI, major TPs as appropriate
	8.2.3.3.3 Air	Required when volatilization is indicated by vapour pressure or Henry's law constant, is observed in laboratory studies of transformation, or when monitoring data indicates the presence of the pesticide in air. For example, this information is most often required for fumigants as they are known to be volatile compounds. May also be required for other compounds regardless of their use pattern given that volatility is inherent to the physical and chemical properties of the compound. Information generated from models predicting the rate of degradation in air may be acceptable. *Test substance*: TGAI, major TPs as appropriate
8.2.3.4	Biotransformation in Soil	Biotransformation studies in soil determine to what extent the pesticide is transformed in microbially active soils and identify the resulting transformation products and transformation pathways. It is recommended that soils relevant to the Canadian environment be used in these studies. For example, studies conducted with volcanic soils, highly weathered soils and paddy soils are not relevant to Canada, and would not satisfy this requirement.
	8.2.3.4.2 Aerobic Soil 20°-30°C	Required for all outdoor and greenhouse uses. This study can provide general insight into the degradation of the pesticide in the environment and is required even if only minimal amounts of the pesticide are expected to come in contact with soil. If possible, the same soils as in the adsorption/desorption studies are to be used. *Test substance*: TGAI, major TPs as appropriate

DACO			Guidance
	8.2.3.4.4	Anaerobic Soil (Flooded) 20°-30°C	Required for some outdoor uses, for example when a pesticide is sprayed on soil or foliage and in situations where a pesticide could leach from a treated material into the surrounding soil (such as seed treatments or granulars). This study furthers the understanding of the transformation of a pesticide by providing insight into its degradation when the treatment area is periodically flooded or poorly drained, or when the assessment of physicochemical properties, mobility and degradation in soil indicates potential migration to subsoil where conditions are anaerobic. The requirement for an anaerobic soil study may be satisfied by an anaerobic water/sediment study (DACO 8.2.3.5.6) if a scientific rationale is provided showing that the environmental behaviour of the pesticide is similar in both systems. *Test substance*: TGAI, major TPs as appropriate
8.2.3.5	Biotransformation in Aquatic Systems		Biotransformation studies in water/sediment systems provide information on the rate of dissipation of the pesticide due to microbial transformation, chemical reactions such as hydrolysis, and the movement of the pesticide between the water column and the sediment layer. These studies also provide information on the identity of the transformation products formed and the transformation pathway.
	8.2.3.5.4	Aerobic Water/Sediment 20°-30°C	Required for greenhouse uses and some outdoor uses when the pesticide application will result in the pesticide entering surface water. For example, this includes pesticides that are applied directly to water, antifouling products that may leach from treated structures into surrounding water, and pesticides that may run off from the application site into adjacent water bodies or drift to non-target aquatic habitats. Pesticides used in a greenhouse can enter surface water through effluent. *Test substance*: TGAI, major TPs as appropriate
	8.2.3.5.6	Anaerobic Sediment/Water 20°-30°	Required for greenhouse uses and some outdoor uses when the pesticide application will result in the pesticide entering surface water (see DACO 8.2.3.5.4) and when the pesticide is expected to move into anaerobic media. For example, would be required when the pesticide is expected to partition to sediment. *Test substance*: TGAI, major TPs as appropriate
8.2.3.6	Special Studies Related to Use-Pattern or Formulation		Special studies related to the transformation of the pesticide may be required when the use pattern or end-use product results in additional concerns/questions regarding fate and persistence. For example, a phototransformation study on wood would be submitted under this DACO to further the fate characterization of wood treatment uses. In other cases, it may be appropriate to carry out transformation studies with the EP when the active ingredient is characterized by very low solubility. *Test substance*: TGAI or EP as appropriate
8.2.4	Laboratory Studies of Mobility		Mobility studies provide information on the potential for a pesticide to migrate away from the site of application to other environmental compartments.
8.2.4.1	Summary		No information is required under this DACO if Tier II and Tier III summaries are submitted under DACO 12.7.

DACO			Guidance
	8.2.4.2	Adsorption/Desorption	Required for all outdoor and greenhouse uses. This information provides insight into the potential movement of the pesticide in the environment and is required even if only minimal amounts of the pesticide are expected to come in contact with soil or water.
	8.2.4.3	Soil Column Leaching	Adsorption and desorption (8.2.4.2) are preferred. If possible, the same soils as in aerobic soil biotransformation studies are to be used. In some cases, it may be necessary to also submit a soil column leaching study (8.2.4.3) with unaged or aged soil to fully characterize the potential mobility of the compound and major transformation products. For example, soil column leaching studies may be useful for substances that degrade during the equilibration period of an adsorption/desorption study. *Test substance*: TGAI, major TPs as appropriate
	8.2.4.5	Volatilization	Required for fumigants or when volatilization is indicated by vapour pressure or Henry's law constant, if observed in laboratory studies of transformation, or if monitoring information indicates the presence of the pesticide in air. Studies conducted with a typical end-use product are acceptable and should be submitted under 8.2.4.6. *Test substance*: TGAI, major TPs as appropriate
	8.2.4.6	Special Studies Related to Use-Pattern or Formulation	Special studies related to the mobility of the pesticide may be required when the use pattern or end-use product results in additional concerns/questions regarding the fate of the pesticide as it moves away from the site of application. Examples of studies that could be submitted include leaching rates for antifouling products, aqueous leaching of treated wood or the leaching potential of slow release formulations. *Test substance*: TGAI or EP, as appropriate
8.3	Field Studies of Dissipation/Accumulation		These studies provide a better understanding of the persistence and movement of a chemical in the Canadian environment under actual use conditions and substantiate the physicochemical, transformation and mobility data from laboratory studies. Laboratory studies examine the various transformation processes in a controlled environment, thereby playing a crucial role in understanding key routes of transformation. Field studies provide insight into the complex interactions occurring under field conditions where physicochemical properties, mobility, weather conditions, abiotic and biotic routes of transformation, etc., simultaneously affect the mobility and overall dissipation of the pesticide.
	8.3.1	Summary	No information is required under this DACO if Tier II and Tier III summaries are submitted under DACO 12.7.

DACO		Guidance
8.3.2	Terrestrial	Required for some outdoor uses in cases where high exposure to the terrestrial environment is expected. This includes all agricultural uses but may also include some non-agricultural uses as well. The application method and rate of application used in the field study must reflect the use pattern of the proposed product. Note that if a spray application study is submitted to support a seed treatment use, bridging information (for example, a small scale study with treated seeds) may be required if concerns are identified with the spray study. The site selected for field studies should be representative of intended major use areas and thus take into consideration the range of soil properties and climate. Refer to DIR2006-01 for additional guidance on terrestrial field dissipation studies. Foreign field studies are considered only if they represent Canadian use conditions. The Ecological Regions of North America Level II map may be consulted in selecting field sites that are acceptable to both Canada and the United States. Organisation for Economic Co-operation and Development (OECD) harmonized guidance on terrestrial field dissipation includes a crosswalk of North American and European ecoregions, and should be consulted in selecting acceptable European sites. *Test substance*: EP
8.3.3	Aquatic	Required for some outdoor uses, for example when the pesticide is applied directly to water or when the pesticide is likely to enter surface water and concerns related to persistence, mobility, aquatic toxicity or bioaccumulation are identified. Aquatic field studies are intended to confirm results of, and validate predictions from, laboratory studies and to indicate pesticide distribution and persistence in aquatic/sediment systems. Studies should simulate water chemistry and sediment characteristics likely to be encountered under proposed Canadian use conditions. *Test substance*: EP
8.3.4	Special Studies Related to Intended Use Pattern	Special studies carried out under field conditions may be required when the use pattern or end-use product results in additional concerns/questions regarding the fate and behaviour of the pesticide. For example, special field studies could include prospective groundwater studies, soil lysimeter studies, and any other field studies that answer specific questions related to the dissipation of the pesticide in the environment. *Test substance*: EP
8.4	Storage, Disposal and Decontamination	
8.4.1	Summary	Required for all uses. The summary should include draft label statements pertaining to storage and disposal of the product and of the container and actions required in case of a spill. Also, if applicable, the summary should include any specific information on the storage conditions that are required to maintain product integrity. Substance: TGAI and EP
8.5	Other Environmental Fate Studies	Any environmental fate study not captured by the above data requirements that may provide additional insight on the fate of the pesticide in the environment. *Test substance*: TGAI or EP as appropriate

DACO	Guidance
8.6 Other Studies/Data/Reports	
8.6.1 Monitoring	Post-registration monitoring data to be submitted if available.
8.6.2 Other	Any information other than monitoring that can provide additional insight on the environmental chemistry and fate of the pesticide.
12.5.8 Foreign Reviews – Environmental Chemistry and Fate	It is highly recommended to include the foreign reviews of submitted studies, when available, to facilitate the review process. This may include study review documents from the United States Environmental Protection Agency (usually referred to as USEPA DERs) or from any other regulatory authority. Foreign risk assessment documents may also be submitted under this DACO. If foreign review documents are unavailable for submission, please indicate which other regulatory authority has completed specific data reviews.
12.7.8 Applicant Generated Study Reviews – Environmental Chemistry and Fate	Required for Joint Reviews. Strongly recommended for other submission types to facilitate the review process. a) For any Canada-only application, study reviews using North American Free Trade Agreement (NAFTA) templates or following the format of organization for OECD Tier II and Tier III summaries are both acceptable. NAFTA evaluation templates are available upon request. These templates are also available on the USEPA website. Monograph guidance related to the format of OECD Tier II and Tier III summaries is also available. b) For Joint Review applications, the OECD format must be followed.

Appendix IV Guidance for Applicants: Environmental Toxicology

Does not apply to USC 3, 12, 15, 19, 24, 26, 28 and 29, for which no environmental data are required.
DACO = Data Code; TGAI = Technical Grade Active Ingredient; EP = End-Use Product; TP = Transformation Product

DACO	Guidance
9.1 Summaries	Summaries submitted under this DACO are intended to highlight issues of interest related to the toxicity of the pesticide to non-target organisms. Information included here should provide context and discussion to assist in the evaluation of the submitted data, and therefore, should not be limited to executive summaries copied from the supporting studies. Information may not be required under this DACO if Tier II and Tier III summaries are submitted under DACO 12.7.
9.2 Non-Target Terrestrial Invertebrates	
9.2.1 Summaries	No information is required under this DACO if Tier II and Tier III summaries are submitted under DACO 12.7.
9.2.3 Earthworms	Earthworms help maintain soil health by breaking down organic matter and mixing the soil layers. These organisms are therefore particularly important in agricultural systems and in other areas where soil health is to be maintained to support plant growth (for example, uses on ornamental plants and on turf).
9.2.3.2 Chronic Toxicity	Chronic studies with earthworms provide information on potential longer-term effects (including reproduction) that may impact population levels or the diversity of the community. Such a study is required for agricultural uses when the pesticide application will result in the pesticide reaching the soil surface or entering the soil below the surface. For example, it would be required for direct-spray applications to soil or to foliage, soil injections, in-furrow applications, granule applications and seed treatments. Chronic studies may not be required if the results of an avoidance test indicate no effects (the avoidance test is not a data requirement, but results from this simple test may be used to support a waiver request). *Test substance*: TGAI, major TPs in soil and EP as appropriate
9.2.4 Bees/Insect Pollinators	Bees and other insect pollinators play a key role in the pollination of crops and other plants in the ecosystem and their biodiversity has intrinsic value to the environment. In addition, honeybees produce honey and other hive products, which are both important for the health of the hive as well as providing food for human consumption. Data requirements follow the tiered approach of the risk assessment framework for pollinators. Initially, Tier I (Screening Level) studies are required; higher tier studies may be required when a potential for risk is identified based on the Tier I risk assessment. For details, please refer to the pollinator risk assessment guidance document found in the Risk Assessment section of the Health Canada Pollinator Protection webpage. Studies should be conducted using the honeybee; tests with other bee species (for example, bumblebees) may also be conducted to provide additional insights into the potential effects of a pesticide on insect pollinators.
9.2.4.1 Bee Adult Acute Contact Toxicity	Adult bees may be acutely exposed to pesticides through direct contact from different sources including spray droplets or dust as the pesticide is applied in the treatment area, from drift off the treatment area, or from residues deposited on the surface of plants on or off the treatment area. This study is required for all pesticides that are used outdoors where bees may forage or nest, and for pesticides used in the greenhouse where bees are used for pollination. Tier I study. *Test substance*: TGAI, and may also include major TP and EP as appropriate

DACO		Guidance
9.2.4.2	Bee Adult Acute Oral Toxicity	Adult bees may be acutely exposed to pesticides through consumption of pesticide-contaminated food sources. Bee food sources can be contaminated when a pesticide is deposited directly on the food source (such as an open flower) during application, when a pesticide is translocated from leaves or roots after application (for example, systemic and persistent pesticides), or when a pesticide is carried into the hive through the activity of foraging bees. This study is required for all pesticides that are used outdoors where bees may forage or nest, and for pesticides used in the greenhouse where bees are used for pollination. Tier 1 study. *Test substance*: TGAI, and may also include major TP and EP as appropriate
9.2.4.3	Bee Larvae Toxicity	Immature bees may be exposed to contaminated food sources being brought back to the hive by foraging bees. A bee larvae toxicity test is required for all pesticides that are used outdoors where bees may forage or nest. This study is also required for greenhouse uses when pollinator colonies are maintained for crop pollination. Tier I study. *Test substance*: TGAI, and may also include major TP and EP as appropriate
9.2.4.4	Bee Adult Chronic Toxicity	Adult bees may be chronically exposed to pesticides by feeding on contaminated food sources over an extended period of time. The bee adult chronic toxicity test is required for all pesticides that are used outdoors where bees may forage or nest. This study is also required for greenhouse uses when pollinator colonies are maintained for crop pollination. Tier I study. *Test substance*: TGAI, and may also include major TP and EP as appropriate
9.2.4.5	Bee Toxicity of Residues on Foliage	This study is used to determine the residual toxicity of a pesticide to bees through contact exposure and may be required when the formulation contains one or more active ingredients having an acute contact toxicity (LD_{50}) less than 11 µg/bee, and the use pattern(s) indicate(s) a potential exposure for bees. Tier II study. *Test substance*: EP
9.2.4.6	Pollinator Semi-Field Study	Semi-field studies are used to determine the effect of a pesticide on bees at the colony/population level under relatively controlled conditions. These studies typically represent worst-case colony exposure conditions for the proposed use. Examples of semi-field studies include tunnel tests, where colonies are confined to the treatment area to ensure that exposure has taken place, and colony feeding studies, where colonies are unrestricted and fed food sources containing known concentrations of pesticides. The level of exposure is expected to be defined (for example, the residue level in the plant, pollen and nectar, bees, and/or hive products is to be reported). Semi-field studies are required when a potential for risk is identified at Tier I and mitigation options do not eliminate potential pollinator risks, or when information from other sources indicates potential risks for pollinators and the risks cannot be eliminated through mitigation. Tier II study. *Test substance*: TGAI or EP, as appropriate

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9.2.4.7	Pollinator Field Study	Field studies are used to determine the effect of a pesticide to bees at the colony/population level under field conditions. These studies typically represent more realistic colony exposure conditions for the proposed use. The level of exposure is expected to be defined (for example, the residue level in the plant, pollen and nectar, bees, and/or hive products is to be reported). Field studies are required when a potential for risk is identified at lower tiers and mitigation options do not eliminate potential pollinator risks, or when information from other sources indicates potential risks for pollinators and the risks cannot be eliminated through mitigation. Tier III study. *Test substance*: EP
9.2.4.8	Residue Study for Pollinators	Residue studies are used to determine the level of a pesticide in various environmental compartments when contact or dietary exposure to bees may occur through sources such as pollen, nectar, leaves, honey and bee bread. This information can be used to refine the Tier I risk assessment for the proposed use. This information may also be used to inform higher tier assessments. Residue studies may be required when a potential for risk is identified at Tier I and mitigation options do not eliminate potential pollinator risks, or information from other sources indicates potential risks for pollinators and the risks cannot be eliminated through mitigation. *Test substance*: EP
9.2.4.9	Other Pollinator Studies	Other types of studies may provide additional insight on the potential effects of a pesticide on pollinators. These studies can include non-guideline but scientifically sound studies, such as studies on proboscis extension reflex, bee hypopharyngeal glands, and information on pollinators and pollination of plants. Other studies are to be submitted when available, or to address a specific concern. *Test substance*: TGAI, major TP and/or EP
9.2.5	Predators	Non-target arthropods other than bees play a beneficial role in ecosystems by controlling insect pests and serve as a food source for other organisms. Predators and parasitoids specifically (also referred to as beneficial arthropods) are important components of integrated pest management programs. Depending on the species, non-target arthropods could be affected when coming in direct contact with spray droplets upon pesticide application, with residues deposited on the surface of plants, residues deposited on the soil surface or residues in the soil itself. For insect-growth regulators and systemic pesticides, dietary exposure may also occur. Studies on non-target arthropods are required for pesticides that are applied in sites that may support integrated pest management programs using natural or introduced biological control agents, such as predators or parasitoids, and/or where exposure to significant natural populations of non-target arthropods could occur and be potentially impacted. Some low-exposure scenarios such as domestic-use sites and disturbed habitats such as cityscapes, urban parks, shelterbelts and rangelands generally would not require these data. For all pesticides that meet the above criteria and are not insect-growth regulators, screening level laboratory tests on glass plates must be conducted using the standard test species *Typhlodromus pyri* (a predator species, DACO 9.2.5) and *Aphidius rhopalosiphi* (a parasitoid species, DACO 9.2.6). Extended laboratory testing with the same test species would also be required if concerns were identified based on results from the screening-level glass plate tests. Extended laboratory testing considers both mortality and reproduction endpoints and may use glass plates, natural substrates (such as leaves), or a combination of the two. In addition, depending on the outcome of the screening level assessment, extended laboratory testing on one or more additional species relevant to the use pattern would be
9.2.6	Parasitoids	

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	required. For spray applications, recommended additional species for extended tests are foliar dwelling species such as *Orius laevigatus*, *Chrysoperla carnea* and *Coccinella septempunctata* and the ground dwelling species *Aleochara bilineata*. For pesticides that are incorporated in soil such as seed treatments and granular pesticides, extended laboratory tests on at least one soil-dwelling species are also required (*Hypoaspis aculeifer* is recommended). Where a screening-level study is not possible for solid formulations (for example, seed treatments or granulars where there is no corresponding spray formulation available), then testing should begin with the extended laboratory tests. Based on the outcome of extended laboratory studies, additional testing using aged residues could be conducted to take into account the degradation of the test substance. For substances with systemic toxicity, additional information may be required that considers both oral and contact exposure. For insect-growth regulators, testing should begin with extended laboratory studies, as these encompass stages of the life cycle of the test species that would be sensitive to the IGR mode of action. Extended tests should be conducted with *Aphidius rhopalosiphi*, *Coccinella septempunctata* and *Chrysoperla carnea*. Tests should not be carried out with *Typhlodromus pyri* as mites are not particularly sensitive to insect-growth regulators. In some instances where a concern has been raised at the screening level, it may be appropriate to exclude extended laboratory studies during subsequent testing and proceed directly to semi-field or field studies (DACO 9.2.9). Such a progression would be on a case-by-case basis and would depend on the questions to be answered. *Test substance*: EP
9.2.7 Other Terrestrial Invertebrates	Examples of other terrestrial invertebrates could include enchytraeids, collembolans or nematodes. In some cases, these groups of invertebrates may react differently than the typical test species and can thus provide additional insight into the toxicity of the pesticide to non-target terrestrial invertebrates. Studies should be submitted if available.
9.2.8 Laboratory Studies with an End-Use Product	Additional studies with the end-use product may be required based on concerns arising from the results of other studies. *Test substance*: EP
9.2.9 Field Studies with an End-Use Product (Other than Pollinators)	If concern is identified from laboratory studies, it may be appropriate to conduct semi-field or field testing to further characterize risk to non-target terrestrial invertebrates. These studies are intended to provide information under actual use conditions. Pollinator semi-field and field studies are submitted under DACO 9.2.4.6 and 9.2.4.7, respectively. For earthworms, field studies are carried out with many earthworm species and investigate the potential recovery at a population level following pesticide application. The duration of the study depends on the characteristics of the test substance, but will typically be of one year. For beneficial arthropods, semi-field studies involve the release of a single species into a caged area that encloses a portion of crop or part of plant grown under normal commercial practices (for example, fruit trees). The choice of crop(s) and test species depends on results from the earlier laboratory and semi-field tests and on expert assessment of where harmful effects are most likely to be observed, with particular emphasis on major uses. *Test substance*: EP

DACO		Guidance
9.3	Non-Target Freshwater Invertebrates	Aquatic invertebrates play an essential role in ecosystem function as they represent an important food source for other organisms and are also involved in breaking down and cycling organic matter and nutrients. Freshwater invertebrates can be exposed to a pesticide when it is applied directly to a freshwater system (such as a lake, river, pond, stream or wetland), when terrestrial outdoor applications result in spray drift or runoff, through the release of effluent or when a pesticide leaches from treated material that is immersed in water.
9.3.1	Summary	No information is required under this DACO if Tier II and Tier III summaries are submitted under DACO 12.7.
9.3.2	*Daphnia* sp. Acute	Required for all outdoor and greenhouse uses. An acute study with *Daphnia* provides basic toxicity information and is required even if only minimal amounts of the pesticide are expected to come in contact with water. *Test substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.3.5)
9.3.3	*Daphnia* sp. Chronic (Life-Cycle)	Required for outdoor uses when the pesticide application can result in the pesticide entering freshwater. This study is intended to identify potential effects on aquatic invertebrates during the reproduction stages of their life cycle. Such effects may be related to short-term exposure during a sensitive life stage or may occur as a result of a prolonged exposure (due to multiple applications or to persistence). *Test substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.3.5)
9.3.4	Laboratory Studies with Other Species	Laboratory tests with freshwater invertebrates other than *Daphnia* sp. may be required for outdoor uses, depending on the properties of the pesticide. For example, sediment toxicity tests with freshwater invertebrate species such as chironomids (*Chironomus* sp.) are required for outdoor uses when pesticides are expected to partition to and persist in sediment once they have entered the aquatic environment (note that toxicity tests during which the pesticide is added to the overlying water phase are generally considered more representative of actual exposure routes than those where the pesticide is added directly to the sediment). *Test substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.3.5)
9.3.5	Laboratory Studies with an End-Use Product	Studies on relevant species of freshwater invertebrates may be required for outdoor uses if there are toxicity concerns associated with the formulated product. A study investigating the acute toxicity of the EP to daphnids or any other relevant species is required when the pesticide is applied directly to a water body. *Test substance*: EP
9.3.6	Field Studies with an End-Use Product	Studies conducted outdoors (microcosm, mesocosm, lentic enclosures, etc.) may be carried out to address specific concerns identified based on results from laboratory studies. Studies investigating effects strictly on freshwater invertebrates are to be submitted under this DACO. When freshwater organisms from multiple taxa are tested in a single test system, studies should be cross-referenced to all relevant DACOs (9.3.6, 9.5.5 and/or 9.8.7, as appropriate). *Test substance*: EP

DACO		Guidance
9.4	Non-Target Marine Invertebrates	Similar to freshwater invertebrates, saltwater species play an important role in ecosystem function and may be exposed to pesticides when they enter marine or estuarine environments through direct application to water, spray drift, runoff, discharge of effluent, leaching from treated materials, etc. Exposure is typically expected when the pesticide is used in coastal areas (coast of British Columbia, Atlantic provinces, along the Estuary and Gulf of the St. Lawrence River), although the movement of the pesticide from freshwater to saltwater systems may also be considered as a potential route of exposure especially if the pesticide is persistent in aquatic systems. Studies with marine species are generally not required when the pesticide is to be used exclusively in the Prairies.
9.4.1	Summary	No information is required under this DACO if Tier II and Tier III summaries are submitted under DACO 12.7.
9.4.2	Acute (Crustacean)	Required for outdoor uses when the pesticide application can result in the pesticide entering estuarine/marine systems. Tests are generally carried out on shrimp species (mysid, pink, brown, white or grass shrimps). Tests on lobster would also be required for aquaculture uses in Atlantic regions; adult lobsters (benthic life stage) and/or lobster larvae (pelagic life stage) are to be tested based on their potential for exposure. *Test substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.4.6)
9.4.3	Mollusk Embryo Larvae	Mollusks are a source of food for other organisms and, given that they are filtering organisms, are considered to be indicator species for biomonitoring as they can accumulate pollutants in their tissues. Acute studies on one of either estuarine/marine mollusk embryo larvae or estuarine/marine mollusk shell deposition are required when the pesticide application can result in the pesticide entering estuarine/marine environments. *Test substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.4.6)
9.4.4	Mollusk Shell Deposition	
9.4.5	Chronic (Mollusk or Crustacean)	This study allows for a better understanding of the effects of a pesticide on the various life stages of saltwater invertebrates. It may be required when outdoor pesticide application can result in the pesticide entering estuarine/marine systems and where concerns are identified based on results from the chronic study with daphnids, from acute tests on marine invertebrates, and also considering the exposure profile of the pesticide (in other words, whether the pesticide will be found in water for a prolonged period of time as a result of multiple applications or due to its persistence). *Test substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.4.6)
9.4.6	Laboratory Studies with an End-Use Product	Studies on relevant species of saltwater invertebrates may be required if there are toxicity concerns associated with the formulated product. Data on the acute toxicity of the EP to a saltwater species (either a mollusk or a crustacean) are required when the pesticide is applied directly to a water body. *Test substance*: EP
9.4.7	Field Studies with an End-Use Product	Studies conducted outdoors (microcosm, mesocosm, lentic enclosures, etc.) may be carried out to address specific concerns identified based on results from laboratory studies. Studies investigating effects strictly on saltwater invertebrates are to be submitted under this DACO. When saltwater organisms from multiple taxa are tested in a single test system, studies should be cross-referenced to all relevant DACOs (9.4.7, 9.5.5 and/or 9.8.7, as appropriate). *Test substance*: EP

DACO		Guidance
9.4.8	Bioconcentration/Depuration (Bivalve or Crustacean)	A bioconcentration study with a bivalve or a crustacean is conducted to assess the potential for accumulation in lower trophic level invertebrate organisms. The typical test species is the oyster, which filters large amounts of sediment. A study is required for outdoor or greenhouse pesticides that are expected to enter the aquatic environment and partition to sediment when the log K_{ow} is greater than or equal to 3. *Test substance*: TGAI, major TPs as appropriate
9.5	Fish	Fish play an important role in the regulation of food web dynamics and nutrient balance in ecosystems. Fish may be exposed to a pesticide when it is applied directly to surface water, when terrestrial outdoor applications result in spray drift or runoff, through the release of effluent, or when a pesticide leaches from treated material that is immersed in water. Fish are also used as a surrogate for amphibians; if required, studies with amphibians are submitted under DACO 9.9.
9.5.1	Summaries	No information is required under this DACO if Tier II and Tier III summaries are submitted under DACO 12.7.
9.5.2	Acute Studies	
9.5.2.1	Cold Water Fish (Rainbow Trout)	Data on at least one species of freshwater fish are required for all outdoor and greenhouse uses to provide basic toxicity information, even if only minimal amounts of the pesticide are expected to come in contact with water. Testing with both cold water and warm water fish are required when the pesticide is expected to enter freshwater habitats through direct application to water, spray drift, runoff, discharge of effluent, leaching from treated materials, etc. Representative test species are the rainbow trout (cold water) and the bluegill sunfish (warm water). *Test Substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.5.4)
9.5.2.2	Warm Water Fish (Bluegill Sunfish)	
9.5.2.3	Other Freshwater Fish Species	Acute laboratory tests with freshwater fish species other than the rainbow trout and the bluegill sunfish may be required for outdoor uses based on the fate characteristics of the pesticide. For example, for pesticides that are expected to partition to sediments following their entry into freshwater systems, laboratory studies that test effects on freshwater fish that are primarily bottom-feeders like the channel catfish or the common carp may be required. Additional test species can also provide insight into the intra-species variation in the toxic response to the pesticide. Studies on any species of fish relevant to Canada should be submitted if available. *Test Substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.5.4)
9.5.2.4	Marine/Estuarine Fish	Acute toxicity studies with saltwater fish are required for outdoor uses when the pesticide application will result in exposure to estuarine/marine habitats through direct application to water, spray drift, runoff, discharge of effluent, leaching from treated materials, etc. The representative species typically used for testing is the sheepshead minnow, but the other species relevant to Canada such as the Atlantic silverside can also be used. *Test Substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.5.4)
9.5.2.4.1	Salinity Challenge	The salinity challenge study evaluates the ability of salmonid smolts to survive in seawater following pesticide exposure in freshwater. A salinity challenge study may be required for outdoor uses when the pesticide application will result in exposure to aquatic habitats and where there are concerns related to the chemical properties of the pesticide (for example, membrane-disrupting compounds that can affect osmoregulation). It is recommended that PMRA be consulted on study protocol. *Test substance*: TGAI

DACO		Guidance
9.5.3	Sublethal and Chronic Studies	
9.5.3.1	Fish, Early Life Cycle Toxicity Test	This test is intended to assess potential lethal and sublethal effects on early life stages of fish from the fertilized egg stage until at least the free-swimming fish stage. It is required when outdoor uses can result in the pesticide entering the aquatic environment. An appropriate species (freshwater, saltwater species or both) is to be selected based on the potential for exposure. *Test Substance*: TGAI, major TPs as appropriate
9.5.3.2	Fish, Life Cycle Toxicity Test	The fish life-cycle test is intended to assess effects of the pesticide on the reproductive ability of the adult as well as the development of the offspring. It is required when there are concerns based on the results of acute toxicity studies or when outdoor uses can result in the pesticide being present in freshwater or estuarine/marine water for a prolonged period of time (as a result of multiple applications or due to the persistence of the pesticide). *Test Substance*: TGAI, major TPs as appropriate
9.5.4	Laboratory Studies with an End-Use Product	Studies on relevant species of freshwater or saltwater fish species may be required if there are toxicity concerns associated with the formulated product. Data on the acute toxicity of the EP to fish (the most sensitive fish species based on tests with the TGAI) are required when the EP is to be directly applied to water. *Test substance:* EP
9.5.5	Field Studies with an End-Use Product	Studies conducted outdoors (microcosm, mesocosm, lentic enclosures, etc.) may be carried out to address specific concerns identified based on results from laboratory studies. Studies investigating effects strictly on fish are to be submitted under this DACO. When organisms from multiple taxa are tested in a single test system, studies should be cross-referenced to all relevant DACOs (9.3.6, 9.4.7, 9.5.5 and/or 9.8.7, as appropriate). *Test substance*: EP
9.5.6	Bioaccumulation	Bioaccumulation studies are intended to assess the ability of an organism to accumulate pesticides from their environment (food, soil, water and air), and are important in assessing the fate of a pesticide. Bioconcentration or bioaccumulation studies with fish are conducted to assess the potential for accumulation in upper-trophic level organisms, and are required for outdoor and greenhouse uses when the pesticide is expected to enter the aquatic environment and when the log K_{ow} is equal to or greater than 3. Specialized tests on species other than fish or aquatic invertebrates can be required on a case-by-case basis; these would be submitted under DACO 9.9.

DACO		Guidance
9.6	Wild Birds	Birds are ubiquitous in the environment and may be exposed to pesticides through many different routes of exposure. The main route of exposure considered for the avian risk assessment is the consumption of food items contaminated with the pesticide, including insects, seeds, fruit and foliage. When pesticides are applied as a spray, contamination could occur when pesticide spray droplets are deposited on insects and plants on the treated area or when spray drift is deposited on insects and plants adjacent to the treatment area. In the case of seed treatments, birds could feed directly on treated seeds. Pesticides formulated as granules may be mistaken as food particles or as a source of grit. Pellets or bait may also be mistaken for food. When the pesticide is systemic (applied as a foliar spray, as a tree injection or used as a seed treatment), the movement of the pesticide inside the plant may lead to the contamination of fruit, seeds and other plant parts that could be consumed by birds. In the case of tree injections, birds could also feed on insects/insect larvae found in the treated tree. Other examples of exposure through the consumption of contaminated food items include birds of prey feeding on dead rodents or other animals targeted by vertebrate control products and birds feeding on contaminated fish. While other routes of exposure such as the consumption of drinking water containing pesticides, inhalation and dermal contact, may also be relevant under certain circumstances, these are considered on a case-by-case basis only.
9.6.1	Summary	In cases other than treated seeds, granules and pellets, no information is required under this DACO if Tier II and Tier III summaries are submitted under DACO 12.7. For treated seed, the following information is required under this DACO: (a) weight of active ingredient (a.i.) per unit weight of seeds (for example, can be reported as g a.i./100 kg seed or mg a.i./kg seed); (b) number of seeds per unit weight of seeds (for example, can be reported as the weight of 1000 seeds or as the number of seeds/kg of seed); (c) number of seeds applied per unit area (also referred to as seeding rate; for example, the number of seeds/ha). In addition, a discussion on factors affecting the availability of the seed (for example, germination time of the seed) and the feeding habits of birds and mammals (for example, avoidance/preference of particular seed types) may provide additional insight into the likelihood of adverse effects from the ingestion of treated seeds. For granules and pellets, the following information is required under this DACO: (a) size distribution of granules or pellets (mm); (b) weight of a.i. per kg of granules or pellets; (c) number of granules or pellets per kg of product; (d) kg of product to be applied per hectare; and (e) type of carrier (for example, type of clay, corn cob or cellulose).
9.6.2	Acute Studies	
9.6.2.1	Oral (LD_{50}) Bobwhite Quail	Data for both species are required when the proposed use pattern or mode of action of the pesticide suggests potential exposure or effects in non-target birds. Examples of exposure routes for birds are provided above (see DACO 9.6). Specifically for aquatic uses, tests with birds are required only if bioaccumulation has been demonstrated (see DACO 9.5.6 for more information on the lines of evidence that are considered when addressing the bioaccumulation potential). *Test substance*: TGAI
9.6.2.2	Oral (LD_{50}) Mallard Duck	
9.6.2.3	Oral (LD_{50}) Other Species	Tests with other species may be required if avian acute oral toxicity is of concern based on results of studies using the bobwhite quail or the mallard duck. For example, a passerine species may be appropriate. *Test substance*: TGAI

DACO		Guidance
9.6.2.4	Dietary (LC_{50}) Bobwhite Quail	Data on at least one test species are required if toxicity was observed in avian acute oral studies (including sub-lethal effects) and/or in avian reproduction studies. Recognizing that these studies are often generated for other jurisdictions, these should be submitted if available. *Test substance*: TGAI
9.6.2.5	Dietary (LC_{50}) Mallard Duck	
9.6.2.6	Dietary (LC_{50}) Other Species	Tests with other species may be required if avian acute dietary toxicity is of concern based on results of studies using the bobwhite quail or the mallard duck. *Test substance*: TGAI
9.6.3	Chronic Studies	Data for both species are required when the proposed use-pattern or mode of action of the pesticide suggests potential exposure or effects in non-target birds. Examples of exposure routes are provided above (see DACO 9.6). The duration of the exposure period should not be used as an argument to support a waiver request since both long and short term exposures are known to lead to avian reproductive effects. *Test substance*: TGAI
9.6.3.1	Avian Reproduction, Bobwhite Quail	
9.6.3.2	Avian Reproduction, Mallard Duck	
9.6.3.3	Avian Reproduction, Other Species	Tests with other species may be required if avian reproduction is of concern based on results of studies using the bobwhite quail or the mallard duck. *Test substance*: TGAI
9.6.4	Laboratory Studies with an End-Use Product	Laboratory studies with the EP may be required if there are toxicity concerns associated with the formulated product.
9.6.5	Field Studies with an End-Use Product	Field or semi-field studies may be required when concerns are identified based on laboratory data. Field studies are conducted to quantify the actual risks in the field or to show that risks in the field under actual use are different than in the laboratory.
9.6.6	Special Studies Related to the Intended Use-Pattern	Examples include food avoidance tests, inhalation studies, and dermal exposure studies. *Test substance*: TGAI or EP as appropriate
9.7	Wild Mammals	Wild mammals are ubiquitous in the environment and may be exposed to pesticides through many different routes. Similar to wild birds, the main route of exposure for wild mammals is considered to be the consumption of food items contaminated with the pesticide, including insects, seeds, fruit and foliage. In the case of pesticides that are applied as a spray, contamination could occur when pesticide spray droplets are deposited on insects and plants on the treated area or when spray drift is deposited on insects and plants adjacent to the treatment area. In the case of seed treatments, mammals could feed directly on treated seeds. Pesticides formulated as granules may be mistaken as food particles or as a source of grit. Pellets or bait may also be mistaken for food. When the pesticide is systemic (applied as a spray, as a tree injection or used as a seed treatment), the movement of the pesticide inside the plant may lead to the contamination of fruit, seeds and other plant parts that could be consumed by mammals. While other routes of exposure such as the consumption of drinking water containing pesticides, inhalation and dermal contact, may also be relevant under certain circumstances, these are considered only on a case-by-case basis.

DACO		Guidance
9.7.1	Summary	Mammalian toxicology data are submitted under Part 4 of the data package. A summary of the data must be provided here for all uses where mammals could be exposed to the pesticide. Examples of exposure routes for mammals are provided above (see DACO 9.7). The summary should include information on the acute and reproductive toxicity of a pesticide to mammals. At the very least, the summary should include results from the oral acute and multi-generation reproduction studies. It should be noted that the toxicity endpoints chosen for use in environmental risk characterization may be different from those used for the toxicology (human health) evaluation. Examples of reproductive endpoints that are relevant for the environmental risk characterization include significant reductions in the average number of pups per dam, number of dams with pups, and pup weight. Developmental endpoints that can affect the ability of offspring to successfully mate and reproduce are also of interest. Possible endocrine effects must also be discussed in the summary.
9.7.2	Field Studies with an End-Use Product	Field studies may be required when concerns are identified based on laboratory data. Field studies are conducted to quantify the actual risks in the field or to show that risks in the field under actual use are different than in the laboratory.
9.7.3	Other Studies	Any other study not captured by the above data requirements that may provide additional insight into the effects of a pesticide on mammals.
9.8	Non-Target Plants	Includes both terrestrial and aquatic species. Testing with ten terrestrial species and up to five aquatic species is required when the proposed use pattern or mode of action suggest potential exposure or effects to non-target plants.
9.8.1	Summary	No information is required under this DACO if Tier II and Tier III summaries are submitted under DACO 12.7.
9.8.2	Fresh Water Algae	Algae are the primary carbon-fixing organisms in aquatic environments, play a critical role in nutrient cycling and are sources of food for other organisms. Toxicity studies with freshwater algae are required when the pesticide can enter freshwater systems through direct application to water, spray drift, runoff, discharge of effluent, leaching from treated materials, etc. The majority of freshwater phytoplankton is made of green algae, diatoms and blue-green algae. Representative species recommended for testing on each of these classes are *Pseudokirchneriella subcapitata* (formerly known as *Selenastrum capricornutum*), *Navicula pelliculosa*, and *Anabaena flos-aquae*, respectively. *Test Substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.8.6)
9.8.3	Marine Algae	Estuarine environments serve as critical feeding and nursery grounds for many marine organisms, including commercial fish and shellfish species. These productive and diverse ecosystems are particularly vulnerable because they act as repositories for pollutants from sources upland. Marine systems are dominated by algae, with few vascular aquatic species present. Toxicity studies with marine algae are required when the pesticide can enter marine/estuarine systems through direct application to water, spray drift, runoff, discharge of effluent, leaching from treated materials, etc. The representative species recommended for testing is the marine diatom *Skeletonema costatum*. *Test Substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.8.6)

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9.8.4 Terrestrial Vascular Plants	Terrestrial plants at the margin of crop fields are important constituents of habitats, providing food and shelter for many organisms. In addition, terrestrial plants stabilize soil, which can reduce the displacement of soil particles in surface water, and also act as windbreakers. Toxicity studies with terrestrial plant species are required when habitats adjacent to treated areas are exposed to spray drift deposit. The required studies investigate both seedling emergence and vegetative vigour. Testing is required for all types of pesticides (not limited to herbicides). Both Tier I and Tier II testing may be carried out (with a single and with multiple exposure concentrations, respectively). Tier II data are required when more than 25% effect on any parameter are exhibited at Tier I. Tier II data may be submitted without Tier I data if effects are expected. Note that studies on terrestrial plants are not required when herbicide products are used for site preparation and conifer release, and on rights-of-way. *Test Substance*: EP
9.8.5 Aquatic Vascular Plants	Aquatic vascular plants provide food and shelter for many organisms. Toxicity studies with aquatic vascular plants are required when the pesticide can enter freshwater systems through direct application to water, spray drift, runoff, discharge of effluent, leaching from treated materials, etc. The representative species recommended for testing is a floating aquatic plant, such as duckweed (*Lemna gibba* or *Lemna minor*). Studies with rooted aquatic vascular plants may also be required on a case-by case basis, for example when the pesticide is expected to accumulate in sediments. *Test Substance*: TGAI, major TPs as appropriate and EP on occasion (refer to DACO 9.8.6)
9.8.6 Laboratory Studies with an End-Use Product	For terrestrial species, additional studies with the EP may be required to address concerns identified based on results from standard laboratory tests. For example, studies investigating the uptake, translocation and movement of a pesticide inside the plant may be required for systemic pesticides. For aquatic species, studies with the end-use product may be required if there are concerns associated with the formulated product. Specifically in cases where the pesticide is applied directly to water, the toxicity to non-target aquatic plants can be addressed with studies with either the EP (this DACO) or the TGAI (DACO 9.8.5). *Test substance*: EP
9.8.7 Field Studies with an End-Use Product	Outdoor studies with terrestrial or aquatic species may be required to address specific concerns identified under controlled conditions. For example, studies may investigate effects at a community level or test additional species under operational conditions (in other words, testing native species exposed to spray drift).
9.9 Other Studies/Data/Reports	These may be required based on the specific characteristics of the pesticide, its mode of action, its use pattern or based on concerns arising from the results of other studies. Examples include bioaccumulation studies carried out with species other than fish, mollusk or crustaceans, mesocosm bioaccumulation studies, toxicity tests carried out with leachate or effluent, toxicity tests on amphibians or any other studies/data/reports that may be relevant. These can be submitted, if available.
12.5.9 Foreign Reviews – Environmental Toxicology	It is highly recommended to include the foreign reviews of submitted studies, when available, to facilitate the review process. This may include study review documents from the United States Environmental Protection Agency (usually referred to as USEPA DERs) or from any other regulatory authority. Foreign risk assessment documents may also be submitted under this DACO. If foreign review documents are unavailable for submission, please indicate which other regulatory authority has completed specific data reviews.

DACO		Guidance
12.7.9	Applicant Generated Study Reviews – Environmental Toxicology	Required for Joint Reviews. Strongly recommended for other submission types to facilitate the review process. a) For any Canada-only application, study reviews using North American Free Trade Agreement (NAFTA) templates or following the format of organization for OECD Tier II and Tier III summaries are both acceptable. NAFTA evaluation templates are available upon request. These templates are also available on the USEPA website. Monograph guidance related to the format of OECD Tier II and Tier III summaries is also available. b) For Joint Review applications, the OECD format must be followed.